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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,582	08/15/2001	Jonathan Stanley Harold Denyer	102199-201	3302

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/930,582	Applicant(s) DENYER ET AL.	
	Examiner Michael G. Mendoza	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-11 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-8,11,13,14,17 and 18 is/are rejected.
- 7) ☒ Claim(s) 9, 10, 15, and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 18 October 2005 have been fully considered but they are not persuasive. The Applicant has amended the claims to change "drug deliveries" to "treatment". The Denyer et al. references read on the new limitation. When a drug is delivered it is a treatment. The Denyer et al references deliver multiple doses of drugs resulting in multiple treatments.
2. The Applicant argued that restriction of claims 13-18 is improper. After further reviewing the claim the Examiner agrees with the Applicant. Claims 13-18 are hereby rejoined and fully examined for patentability under.

Since all claims previously withdrawn from consideration have been rejoined, the restriction requirement made in the Office action mailed on 18 May 2005 are hereby withdrawn.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 1, 3, 5, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Denyer et al. 6192876

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

5. Denyer et al. teaches a system for delivery of a drug to a patient comprising: a drug delivery device arranged to delivery a dose of the drug to the patient over a plurality of breaths, the device including a breath analyzer which (i) analyses a patient's breathing during the drug delivery, wherein the analysis by the breath analyzer includes quantitatively measuring at least one parameter of the patient's breathing; and (ii) generates breath information on a patient's breathing during drug delivery wherein the breath information includes the at least one quantitative measurement of the patient's breathing (col. 3, lines 21-33); a data carrier; a data analyzer and a trend generator (col. 3, lines 57-63); and means for identifying non-compliant use of the drug delivery device (col. 3, lines 54-56).

6. Claims 1, 6-8, 13, 14, 17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Denyer et al. 6584971.

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

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under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

7. Denyer et al. teaches a system and method for delivery of a drug to a patient comprising: a drug delivery device arranged to delivery a dose of the drug to the patient over a plurality of breaths, the device including a breath analyzer which (i) analyses a patient's breathing during the drug delivery, wherein the analysis by the breath analyzer includes quantitatively measuring at least one parameter of the patient's breathing; and (ii) generates breath information on a patient's breathing during drug delivery wherein the breath information includes the at least one quantitative measurement of the patient's breathing (col. 3, lines 28-39); a data carrier (col. 3, lines 34-35); a data analyzer (col. 3, lines 36-37) and a trend generator (col. 7, lines 17-21); and wherein the breath information includes inhalation time and a total number of pulses, and wherein the breath information includes inhalation time and a total number of pulse, and wherein the data analyzer calculates a mean inhalation time value by dividing the total inhalation time by the total number of pulses (col. 1, line 63 – col. 2, line 16); wherein the breath information includes inhalation time and exhalation time and wherein the date analyzer calculates an inhalation to exhalation ratio value by dividing the total inhalation time by the total exhalation time (col. 11, lines 17-28).

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Allowable Subject Matter

8. Claims 9, 10, 15, and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

12/27/05